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EXAMINER

CUTLIFF, YATE KAI RENE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,374	Applicant(s) RONGIONE ET AL.	
	Examiner YATE' K. CUTLIFF	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2, 4 - 6, 8, 10 - 20 and 23.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 4 - 6, 8, 10 - 20 & 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 4 - 6, 8, 10 - 20 & 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/12/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 2, 4 - 6, 8, 10 - 20 and 23 are pending.
Claims 1, 3, 7, 9, 21 and 22 have been canceled
Claims 2, 4 - 6, 8, 10 - 20 and 23 are rejected.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 18, 2010 has been entered.

Information Disclosure Statement

3. Receipt of the Information Disclosure Statement filed on May 21, 2010 is acknowledged and considered. Further, a typographical error in the WP 03043972 is noted and the correct to the reference number WO 03043972.

Response to Arguments

4. Applicant's arguments, see pages 5 - 12, filed May 18, 2010, with respect to the rejection(s) of claim(s) 1, 2, 4-8 and 10 - 20 under 35 USC 103(a) have been fully considered and are persuasive in view of the claim amendments, claim cancellations and arguments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection claims 2, 4 - 6, 8 , 10 - 20 and 23 is made in

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view of Knoer (US 3,644,179), Cosgrove et al. (US 5194,640), Ghisalberti (WO 2001/18161), Reaney et al. (US 6,420,577), Baltes et al. (US 3,162,658), Saebo et al. (US 6,410,761), Kirk-Othmer (4th Ed. 1993) and Sachtler (US 5,326,925).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8 and 23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 8, line 8, the following is set out: "thin film or wiped film evaporator connected to a fractionation column". Also, in claim 23, lines 5-6, the following is set out: "thin film or wiped film evaporator connected to a fractionation column". Applicant directs the Examiner to [0049] - [0051] to show support for the amendment in claim 8 and language of claim 23. The Examiner notes that in these paragraphs, the specification references that the fractionating column may be used as part of the distillation apparatus. However, at paragraph [0079] distillation is disclosed as taking place in a unit consisting of a thin film evaporator connected to a rectification column with 10 inches of packing. It is not clear whether Applicant is using the terms rectification column and fractionating column interchangeably, because no definition or clarification is set out in the specification.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 23 and 2, 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoer (US 3,644,179), in view of Cosgrove et al. (US 5194,640) and further in view

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of Ghisalberti et al. (WO 2001/1816), Reaney et al. (US 6,420,577) and Saebo et al. (US 6,410,761).

12. Rejected claim 23 cover, inter alia, a process to refine a conjugated linoleic acid-containing material comprising: introducing a first ester stream comprising c9,t11 and t10,c12 isomers of conjugated linoleic acid esters and unconjugated linoleic acid components into a distillation apparatus, wherein the distillation apparatus is a thin film or wiped-film evaporator connected to a fractionating column, the fractionating column including a heater operated at a temperature in the range of 240° C to 270° C; distilling the first ester stream in the distillation apparatus to produce a second ester stream, wherein the second ester stream is enriched in the c9,t11 and t10,c12 isomers of the conjugated linoleic acid esters and reduced in the unconjugated linoleic acid components compared to the first stream.

Dependent claims 2 and 4-6 further limit the process conditions.

13. Knoer et al. discloses a method and apparatus for continuous fractionation of tall oil and similar mixtures of organic substances containing, components prone to react upon heating. The apparatus contains one or more fractionating columns with a pretreating device comprising an evaporator, wherein the evaporator is a thin film evaporator (low residence time apparatus). (see abstract and figure). It is disclosed that with the use of high-speed evaporating greater yields of the desired main fractions are realized and the fractions have better quality. (see col. 1, lines 15 - 19). Knoer et al. states that during the distillation of tall oil and similar complex mixtures of organic compounds some valuable constituents such as the fatty acids are lost due to the

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formation of high boiling substances. Also, that it is known that in tall oil and other similar mixtures of organic substances there are components which react with the desired end products to form compounds of increased molecular weight, for example, by esterification, thereby reducing the yield and quality of the main fractions resulting from fractionation. (see col. 1, lines 20 - 29). Knoer et al. solves the problem of undesirable reactions taking place during distillation by applying thin film evaporation with extremely short heating contact. (see col. 1, lines 72 - 75). The process of Knoer's thin film evaporator and fractionation column were operated under pressure conditions of 35 to 65 mm Hg. (see col. 3, lines 1 - 20). The process of Knoer et al. is set out in column 4 as set out below.

The crude product, for example, tall oil, is passed through line 10 into the first evaporating stage I, that is, an apparatus 12 which has here been shown to comprise a thin film evaporator 50, such as a Luwa evaporator, a rectifier 51 and a condenser 52. In this evaporator 50 the crude feed is subjected for a time of between about 3 and 10 seconds, preferably about 4 seconds, to a temperature of between about 150° and 250° C., preferably about 180° C. In this pretreating apparatus 12, the feed is deodorized and degassed, and water and the light ends are removed by fractionation. The malodorous substances, the gas and the most volatile compounds of the light ends as well as the water are withdrawn through line 14 from the pretreating device 12. The main portion of the relatively easily vaporized components of the light ends which accumulate in the fractionating column of the pretreating device 12 is withdrawn through the line 16.

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The residual mixture containing the heavy ends and intermediate constituents which has been pretreated in the manner described is fed through line 18 to the treating step II. This is carried out in an apparatus 15 including a thin film evaporator 20 and separators 53 and 54 and a fractionating column 26 provided with several condensers 58 and 59, thin film evaporator means 55 and separators that is to say, stripper means 56 and rectifier means 57, 60 incorporating a main rectifier 57 and further rectifier 60. In apparatus 20 the normally vaporizable components of the mixture are separated from the heavy ends which are withdrawn as residue through line 24. The vapors formed pass through the separators 53 and 54 into the fractionating column of the apparatus column 26. In the stripping section 56 of this column a fraction is accumulated and withdrawn through line 30, this fraction being rich in rosin acids. Heavy ends, whose components either may have been entrained in the vapors entering through line 22 or may have been formed anew in the fractionating column 26 are accumulated in the lowest part of this column together with a considerable percentage of rosin acids and are preferably withdrawn from the bottoms outlet and returned through line 32 to the inlet side of thin film evaporator of apparatus 20. Thus, in effect, these bottoms are recycled.

In the rectifying section incorporating the main rectifier 57 of the fractionating column 26, another fraction is accumulated and partly condensed by a condenser 58, the condensate being removed through line 34. The uncondensed part of the vapors is rectified by the further rectifier 60 in the uppermost part of the column, condensed and withdrawn through line 28.

A further treatment step III may be included and is preferred. With such an embodiment the apparatus may be arranged exactly like the apparatus for treatment step II, like reference numerals thus being generally used for the same or analogous components, with the feed to the fractionating column 36 being shown as the distillate 34 from the fractionating column 26, although the fractions withdrawn through lines 28, 30 or 34 may be further fractionated by passing one or more of them into the apparatus 36. The various fractions removed in the fractionating column 36 are designated by the lines 38, 40 and 42.

Specifically, in the figure, under the II heading a thin film evaporator 20 is connected to fractionating column 26. (see col. 4 lines 18 – 22). After the subjecting the tall oil to the fractionating column and thin film evaporator the various fractions are removed, with the table showing that the feed 40, contains 97% fatty acids from the tall oil.

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14. The difference between Applicant's claimed process and Knoer et al. is the following: using Applicant's claimed distillation process to produce where the first stream comprising c9,t11 and t10,c12 isomers of conjugated linoleic acids is distilled and produces a second ester stream enriched in c9,t11 and t10,c12 isomers of conjugated linoleic acid esters.

15. However, according to Cosgrove et al. tall oil consist of a mixture of fatty acids where 40 to 50% of the fatty acid is oleic acid while another 35 to 45% is linoleic acid. (see col. 1, lines 21 - 25).

Further, according to the teachings of Knoer et al. their process will increase the yield of the tall oil fatty acid and the quality. (see col. 1, lines 15 - 19). As such, the tall oil fatty acid produced in the process of Knoer et al. would be of higher quality this means that the fatty acid will be further enriched with oleic acid and linoleic acid. Also, the process of Knoer sends a first stream of 18 which contains the intermediate constituents, made up of rosin acid and tall oil fatty acid. The first stream is carried to an apparatus that includes a thin film evaporator 20 and a fractionating column 26. A rosin acid fraction (side product) 30 is withdrawn from fractionating column 26 and another remaining fraction is moved through line 34 into rectifier means 57 containing fractionating column 36, yields a fraction (second stream) containing 97% tall oil fatty acid at line 40.

16. The Examiner noting that Knoer et al. does not specifically, discuss the refining of material comprising conjugated linoleic acid, however, the problem being solved by the process of Knoer et al. is similar to the problem seeking to be solved by Applicant's

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claimed process. That is reducing the reactions that are prone to occur during the distillation of organic substances which contain components prone to react upon heating at high temperatures for prolonged periods, while increasing the yield and quality of the fractionated product. For this reason the Examiner combines the process of Knoer et al. with that of Ghisalberti.

17. Ghisalberti discloses a process for the preparation of conjugated linoleic acid (CLA) where the term CLA includes the ester form of conjugated linoleic acid. (see page 4, lines 13-16). The process produces a product enriched in CLA isomers where c9,c11, c9,t11 and c10,c12 and t10,c12 are most abundant in the mixed CLA. (see page 8, lines 5-11). In the process of Ghisalberti, in order to obtain high grade CLA the product is refined by conventional refining techniques which include stripping as vacuum distillation techniques or the like. (see page 7 lines 24-25 to page 8 lines 1-3). This can be interpreted to mean any conventional refining technique known in the art at the time of the Ghisalberti process.

It was known in the art at the time of Applicant's claimed process that an apparatus that connected a thin film evaporator to a fractionating column as taught by Knoer et al., was useful to refine and separate organic substances prone to react upon heating; and that such an apparatus was capable of increasing the yield and quality of the obtained fractions. Additionally, it was known in the art at the time of Applicant's claimed process that organic substances containing conjugated linoleic acid (CLA) are prone to reactivity under prolonged heating above 226°C according to Example 19 of Reaney et al., and above 200°C according to the teaching of Saebo et al. at col. 10,

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lines 31 – 35). Also, based on the teachings of Reaney et al. and Saebo et al. there are a limited number of distillation processes that can be conducted on compositions containing CLA or there alkyl esters; which will not cause a reaction that changes the composition of the product being distilled and will not reduce the yield of the desired CLA composition. Ghisalberti discloses that high grade CLA can be further refined by conventional techniques that were known in the art at the time of the Ghisalberti process. One such technique for refining composition having properties that are prone to react under high heat for prolong periods of time during fractionation, like CLA, at the time of Ghisalberti was taught by Knoer et al.

In light of the limited refining methods available for refining compositions containing CLA or its alkyl esters, without causing reactions to occur during the refining process, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try and refine compositions containing CLA or CLA alkyl esters of Ghisalberti, by the process taught by Knoer et al. in an attempt to increase yield, and reduce the formation of products produced by prolonged heating during distillation, because one of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common senses.

Furthermore, “Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed. ” KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 1397 (2007). Thus a

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reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

18. Claims 8, and 10 - 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saebo et al. (US 6,410,761), in view of Baltes et al. (US 3,162,658), in view of Knoer (US 3,644,179), in view of Cosgrove et al. (US 5,194,640), in view of Reaney et al. (US 6,420,577), in view of Kirk-Othmer (4th edition, vol. 10, 1993) and further in view of Sachtler (US 5,326,925).

19. Rejected claim 8 covers, inter alia, a process to produce a refined conjugated linoleic acid-containing material, comprising: transesterification of a linoleic acid-containing oil to generate a composition containing linoleic acid esters; isomerization of the composition containing linoleic acid esters to form a first stream containing c9,t1 and t10,c12 isomers of conjugated linoleic acid esters; and distillation of the first stream in a distillation apparatus containing a thin film or wiped-film evaporator connected to a fractionating column, the fractionating column including a heater operated at a temperature in the range of 240° C to 270° C, to produce a second stream, wherein the second stream resulting from the distillation is enriched in the c9,t11 and t10,c12 isomers of conjugated linoleic acid esters compared to the first stream.

Dependent claims 10 - 16 further limit the reactants and reaction conditions.

Dependent claims 17 - 20 are drawn to the work up and optimization of the process.

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20. Saebo et al. discloses process for producing a novel composition of conjugated linoleic acid (CLA) ester with the isomers c9,t11-octadecanoic acid ester and t10,c12 – octadecanoic acid ester, that were obtained by the direct isomerization of an unrefined linoleic acid. (see column 6, lines 16 - 23). Additionally, in Example 9 a process for large scale batch production of conjugated safflower fatty acid methyl ester is taught. The process of Example 9 is a two step process involving the first step of methanolysis (transesterification), and the second step of conjugation (isomerization). Table 15 and 16 disclose the resulting CLA esters having a greater amount of c9,t11 and t10,c12 isomers. (see peak #s 9 and 10). In Example 9 transesterification is completed sequentially, with transesterification taking place first, side products are removed, then the alcohol and alkali alcoholate catalyst are added to the reactor to conjugate the ester. Basically, the transesterification and the isomerization take place in different reaction zones. The conjugation (isomerization) step of Example 9 is conducted at a temperature of 120°C using KOCH₃. Even though Example 9 does not show that the conjugated safflower fatty acid methyl ester was further purified after the conjugation reaction, the general teaching of Saebo et al. discloses that purification by distillation of the derived novel conjugated linoleic acid-containing compositions may be conducted. (see column 3, lines 66-67 to column 4, lines 1-13).

The isomerization process of Saebo et al. is a nonaqueous system. (col. 3, lines 66 - 67 to col. 4 lines 1 - 6). The process uses sunflower, safflower, corn, soybean or linseed oil. (see col. 4, lines 52 – 58). The isomerization process uses alcoholate catalysts such as sodium or potassium ethoxide, or their methyl, butyl or propyl

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counterparts. (see col. 12, lines 53 – 55). Also, an alkali of the catalyst can be used which is an inorganic alkali or an organic alkali. (see col. 9, lines 42 – 46). In Examples 8 and 9 the catalyst of KOCH₃ is provided in methanol. (see col. 22). According to the teachings of Saebo et al. the nonaqueous alkali isomerization process is conducted within a temperature range of 130 to 165°C. (see col. 9, lines 35 & 48 – 49).

21. The difference between Applicant's claimed process and Saebo et al. is as follows: distillation of the first stream in a distillation apparatus containing a thin film or wiped-film evaporator connected to a fractionating column, the fractionating column including a heater operated at a temperature in the range of 240° C to 270° C, to produce a second stream, wherein the second stream resulting from the distillation is enriched in the c9,t11 and t10,c12 isomers of conjugated linoleic acid esters compared to the first stream; the catalyst is a calcium cation; that catalyst base is solid; transesterification and isomerization steps performed in one reaction vessel concurrently or sequentially without an intervening distillation step; the linoleic acid containing oil being grape seed oil, cotton seed oil or sesame oil and the use of a dual reaction zone for the transesterification and isomerization.

22. However, with regard to Applicant's claimed distillation step that includes the use of an apparatus containing a thin film or wiped-film evaporator connected to a fractionating column, the Examiner turns to the teaching of Knoer et al. The process of Knoer et al. discloses a method and apparatus for continuous fractionation of tall oil and similar mixtures of organic substances containing, components prone to react upon heating. The apparatus contains one or more fractionating columns with a pretreating

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device comprising an evaporator, wherein the evaporator is a thin film evaporator (low residence time apparatus). (see abstract and figure). It is disclosed that the use of high-speed evaporating greater yields of the desired main fractions are realized and the fractions have better quality. (see col. 1, lines 15 - 19). Knoer et al. states that during the distillation of tall oil and similar complex mixtures of organic compounds some valuable constituents such as the fatty acids are lost due to the formation of high boiling substances. Also, disclosing that it is known that in tall oil and other similar mixtures of organic substances there are components which react with the desired end products to form compounds of increased molecular weight, for example, by esterification, thereby reducing the yield and quality of the main fractions resulting from fractionation. (see col. 1, lines 20 - 29). Knoer et al. solves the problem of undesirable reactions taking place during distillation by applying thin film evaporation with extremely short heating contact. (see col. 1, lines 72 - 75). The process of Knoer's thin film evaporator and fractionation column were operated under pressure conditions of 35 to 65 mm Hg. (see col. 3, lines 1 - 20). Specifically, in the figure, under the II heading a thin film evaporator 20 is connected to fractionating column 26. (see col. 4 lines 18 - 22). After the subjecting the tall oil to the fractionating column and thin film evaporator the various fractions are removed, with the table showing that the feed 40, contains 97% fatty acids from the tall oil. Applicant is directed to paragraph 13 above for the full discussion of Knoer et al.

23. Knoer et al. does not specifically teach that tall oil fatty acids have linoleic acid, however, Cosgrove et al. discloses that tall oil consist of a mixture of fatty acids where 40% to 50% of the fatty acid is oleic acid while another 35 to 45% is linoleic acid. (see

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col. 1, lines s21 - 25). Also, by following the separation process of Knoer et al. as set in the disclosure at col. 4, lines 19 - 59, the following is taught. Knoer sends a first stream of 18 which contains the intermediate constituents, made up of rosin acid and tall oil fatty acid. The first stream is carried to an apparatus that includes a thin film evaporator 20 and a fractionating column 26. The thin film evaporator has temperatures ranging from 150 to 250°C. A rosin acid fraction (side product) 30 is withdrawn from fractionating column 26 and another remaining fraction is moved through line 34 into rectifier means 57 containing fractionating column 36, yields a fraction (second stream) containing 97% tall oil fatty acid at line 40.

24. Additionally, the Examiner noting that Knoer et al. does not specifically, discuss the refining of material comprising conjugated linoleic acid, however, the problem being solved by the process of Knoer et al. is similar to the problem seeking to be solved by the distillation step of Applicant's claimed process. That is reducing the reactions that are prone to occur during the distillation of organic substances which contain components prone to react upon heating at high temperatures for prolonged periods, while increasing the yield and quality of the fractionated product. Further, the problems of batch distillation seeking to be solved by Applicant's process is recognized by Saebo et al., in that it references the importance of avoiding a purification process that involves distillation at high temperatures for several hours because the heat will cause further reaction of the CLA composition, and produce reduction of yield and reduced quality of the products. (see col. 10, lines 27 – 40).

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25. It was known in the art at the time of Applicant's claimed process that an apparatus that connected a thin film evaporator to a fractionating column as taught by Knoer et al., was useful to refine and separate organic substances prone to react upon heating; and that such an apparatus was capable of increasing the yield and quality of the obtained fractions. Additionally, it was known in the art at the time of Applicant's claimed process that organic substances containing conjugated linoleic acid (CLA) are prone to reactivity under prolonged heating above 226°C according to Example 19 of Reaney et al., and above 200°C according to the teaching of Saebo et al. at col. 10, lines 31 – 35). Further, It was known in the art at the time of Applicant's claimed process that batch distillation at high temperatures for several hours, because the heat causes further reaction of the CLA composition, and cause reduction of yield and reduced quality of the products.

Also, based on the teachings of Reaney et al. and Saebo et al. there are a limited number of distillation processes that can be conducted on compositions containing CLA or there alkyl esters; which will not cause a reaction during distillation that changes the composition of the product being distilled and will not reduce the yield of the desired CLA composition.

In light of the limited refining methods available for refining compositions containing CLA or its alkyl esters, without causing reactions to occur during the refining process, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try and refine compositions containing CLA or CLA alkyl esters of Saebo et al., by the process taught by Knoer et al. in an attempt to increase

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yield, and reduce the formation of products produced by prolonged heating during distillation, because one of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common senses.

Furthermore, "Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed. " KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 1397 (2007). Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

26. With regard to the catalyst of isomerization having a calcium cation the Examiner turns to the teaching of Baltes et al. The Baltes et al. reference discloses a nonaqueous isomerization process for the production of conjugated poly-ethenoid acids and uses the following alkali metals for the alcoholate catalyst: cesium, rubidium, potassium, sodium, lithium, magnesium and zinc. (see column 2, lines 39-45). Baltes et al. does not specifically teach the use of calcium, however, it does disclose the use of magnesium which is in the same periodic group, as such one having ordinary skill in the art at the time of Applicant's claimed process would have been motivated to vary the isomerization process by using calcium as a cation for the alkoxide as a matter of

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choice based on such factors as the success of other family members in the isomerization reaction.

27. With regard to the catalyst base being solid, and transesterification and isomerization steps performed in one reaction vessel; the Examiner turns to the teaching of Baltes et al. The Baltes et al. reference discloses a nonaqueous isomerization process for the production of conjugated poly-ethenoid acids and uses the following alkali metals for the alcoholate catalyst: cesium, rubidium, potassium, sodium, lithium, magnesium and zinc. (see column 2, lines 39-45). It is stated that organic alkali metal compounds can be used as catalyst. Also, in Example 1 of Baltes, the process uses dried potassium methylate (solid), along with reactants of methyl ester of soya bean fatty acids containing linolenic acid and linoleic acid, combined as ester, with isomerization and transesterification taking place at the same time in one reaction vessel.

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention to produce a refined conjugated linoleic acid-containing material as suggested by the process of Saebo et al. and modify the isomerization as suggested by the process of Baltes, to achieve the claimed invention. As disclosed in Saebo et al. motivation for the combination would be to provide a starting point for design of the individual process for the production of the desired compositions containing conjugated linoleic acid.

Therefore, the invention as a whole was *prima facie* obvious because a person of ordinary skill in the art at the time the invention was made, would have been motivated

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to combine the prior art of Baltes to achieve the claimed invention and that there would have been a reasonable expectation of success.

28. With regard to the linoleic acid containing oil being grape seed oil, cotton seed oil or sesame oil the Examiner turns to the teaching of Reaney et al. The Reaney et al. reference teaches the process for the commercial preparation of conjugated linoleic acid from linoleic acid rich oils such as cotton seed, cucumber, grape seed, corn, safflower, soybean, sunflower or walnut or any other vegetable oil. Reaney et al. does not teach the use of sesame oil. However, based on Kirk-Othmer sesame oil contains about 43.2 percent linoleic acid. (see page 267 Table 2). Thus, these limitations are deemed to be obvious absent a showing of unexpected results.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35USC 103(a).

29. With regard to the use of a dual reaction zone apparatus where the transesterification and isomerization steps occur concurrently, Sachtler discloses a process in Example 3 that uses a dual zone reaction system in its isomerization process. Even though the process of Sachtler does not involve the isomerization of an identical composition, however, it has been held that a prior art reference be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem

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with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *in re Oetiker*, 997 F.2d 1443, 24 USPQ 1443 (Fed. Cir. 1992). In this case, applicant is concerned with isomerization of one form of linoleic acid ester to form another form of the linoleic acid ester, while Sachtler was concerned with the isomer 2,3-dimethylbutane. In Sachtler the effluent of a single reaction zone provided the feed for the second reaction zone. As such, it would have been obvious to one of ordinary skill at the time of the claimed invention, knowing that the transesterification and isomerization process can occur sequentially, that a dual reaction apparatus would be successful based on its successful use in the isomerization process of Sachtler. Basically, Applicant's transesterification product (linoleic acid ester) provided feed to the second reaction zone where isomerization would take place.

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. In *re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991).

Additionally, Saebo et al. in Example 9 basically teaches a batch process where the transesterification step takes place first then the isomerization step takes place next in the reactor. The court has held that claimed continuous operation would have been

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obvious in light of the batch process of the prior art. Therefore, this limitation is considered obvious absent a showing of unexpected results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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